

REMARKS

In paragraph 2 of the aOffice Action, claims 1, 9-13, 17-20, 26-30 and 34 were rejected under 35 U.S.C. §102(c) as being anticipated by Shah et al. (Shah).

Reconsideration is requested.

Shah is limited to the disclosure of a composition of hyaluronic acid or a salt thereof, such as hyaluronic acid sulfates and a blocked polyisocyanate in a solvent. The Shah compositions are disclosed as being useful for application onto solid polymeric substrates including a polyurethane substrate for the purpose of creating a coating on the surface of the substrate using conventional coating methods. The Shah process is practiced on a polyurethane substrate by allowing the solvent to evaporate and the coating is cured. After the coating is cured, the resulting coated and cured substrate differ from the claimed covalent bound compound because Shah directs one to rinse or soak his coated product to remove any uncomplexed polymers. The only modified polyurethane product that can result when the Shah coating technique is applied to a solid polyurethane surface would be a molecular layer where the hexamethylene diisocyanate of the Shah composition is attached to the outer surface of a solid polyurethane. This is not a compound *per se* as is pointed out in the present claims as at most it is a chemically modified surface which cannot be employed in the same manner that the compound of claim 1 can be used, namely, for making a solid article or as a coating composition. No method is given for isolation of any compound from the surface described by Shah. The Shah patent does not disclose anything that suggests that a compound could be formed where the polyurethane is covalently bound to an O-sulphated hyaluronic acid.

The Shah patent was applied for on September 30, 1998 while the present application has a priority date of February 25, 1998. For this reason, Shah is not prior art against the present application. Attached to this Amendment is a certified English translation of Italian Patent Application Serial No. PD98A 000037, filed February 25, 1998. The priority of this application was claimed in PCT/EP99/00781, filed February 24, 1999, which is the basis of the present Section 371 Application.

The translation of the priority document at page 6, lines 16-17 and in claim 1, recites that the haemocompatible derivatives are constituted by a polyurethane covalently bound to sulphated hyaluronic acid. Claim 2 of the certified translation recites that the haemocompatible derivatives are sulphated on the hydroxy groups of hyaluronic acid which means that they are O-sulphated as noted at page 6, lines 16-19 of the specification.

Support for claim 9 and 10 on file may be found in claim 1 of the certified translation

Support for claims 11 and 12 may be found in claims 13 and 14, of the certified translation,

Support for claim 13 may be found in claim 13 of the certified translation,
Support for claims 14,15, 16 may be found in claims 15, 16, 17, of the certified translation
Support for claim 17 may be found in claim 18 of the certified translation.
Support for claim 18 may be found in claim 19 of the certified translation.
Support for claim 19 may be found in claim 20 of the certified translation.

As regards product by process claim 20, and the other dependent claims, they are supported by claims 1, 6, 7 and 13-19 of the certified translation. It follows therefore that the applicants are entitled to an effective filing date of February 25, 1998. Since this date antedates the September 30, 1998 filing date of Shah, that reference may no longer be relied upon as prior art. For these reasons, it is requested that this ground of rejection be withdrawn.

In paragraph 3 of the Office Action, claims 2, 6, 8 and 25 were rejected under 35 U.S.C. §103(a) as being unpatentable over Shah.

Reconsideration is requested.

The Shah patent has been distinguished from the claimed invention above. In addition, it has been noted that the sulphated hyaluronic acid which is not on the surface, as is the claimed covalent compound, will in a hydrophilic environment migrate to the surface and will thus increase its concentration at the biological system material interface. This provides improved properties in terms of platelet adhesion, coagulation time etc. As reported in Examples 1-3, 6, 7 and 11 of the present specification, the properties of the claimed compound are improved with regard to anticoagulant activity.

As noted above, the present application is entitled to an effective filing date of February 25, 1998, and the rejection over Shah should be withdrawn. For these reasons, it is requested that this ground of rejection be withdrawn.

In paragraph 4 of the Office Action, claims 1, 9, 10, 13, 17-20, 26, 27 and 30 were rejected under 35 U.S.C. §102(a) as being anticipated by WO98/45335 and in paragraph 5 of the Office Action, claims 1, 2, 5, 9-21, 243 and 26-34 were rejected under 35 U.S.C. §103(a) as being unpatentable over WO98/45335.


Reconsideration is requested.

WO98/45335 only shows a surface reaction between a hyaluronic acid derivative and a solid surface which in the case of Example 8 of WO98/45335 may be a solid polyurethane surface. The resulting product is a surface having a layer of a product that is not a covalently bound compound which may be used as a coating or to make biocompatible materials. In addition, WO98/45335 has a filing date of April 3, 1998 which is after the priority date of the present application. The certified

translation of the attached priority document supports the applicant's claim to an effective filing date of February 25, 1998. For these reasons, it is requested that this ground of rejection be withdrawn.

An early and favorable action is earnestly solicited.

Respectfully submitted,



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